The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

Paper No. 24

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte JACK A. ROTH, DE WEI CAI, and TAPAS MUKHOPOADHYAY

Appeal No.
Application

HEARD:
June 12, 2001

Before WILLIAM F. SMITH, ROBINSON and ADAMS, Administrative Patent Judges.

WILLIAM F. SMITH, Administrative Patent Judge.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 from the final rejection of claims 9 through 11 and 26 through 47, all the claims remaining in the application.

Claims 9, 10, and 26 are representative of the subject matter on appeal and read as follows:

9. A pharmaceutical composition comprising:
(i) an expression construct comprising a first promoter functional in eukaryotic cells and a first nucleic acid encoding a p53-specific ribozyme, wherein said first nucleic acid is under transcriptional control of said promoter; and

(ii) a pharmaceutically acceptable buffer, solvent or diluent.

10. The pharmaceutical composition of claim 9, wherein said expression construct further comprises a second nucleic acid encoding a functional p53 wherein the second nucleic acid transcript is not cleaved by said ribozyme.

26. A method for treating a mammal with cancer comprising the steps of:
(i) identifying a mammal having a cancer characterized by cells expressing a mutated, p53 product;
(ii) providing an expression construct comprising (a) a first promoter functional in eukaryotic cells and a first nucleic acid encoding a p53-specific ribozyme, wherein said first nucleic acid is under transcriptional control of said first promoter and (b) a second nucleic acid encoding a functional p53 product, wherein the transcript from said second nucleic acid is not cleaved by said ribozyme; and
(iii) contacting said expression construct with cancer cells in said mammal, whereby said ribozyme and said functional p53 products are expressed in said contacted cells, said ribozyme cleaving the transcript encoding said mutated p53 product.

The references relied upon by the examiner are:

Orkin et al. (Orkin), "Report and Recommendations of the Panel to Assess the NIH Investment in Reasearch on Gene Therapy," National Institutes of Health (Dec. 1995)

Christoffersen, et al. (Christoffersen), "Ribozymes as Human Therapeutic Agents." Journal of Medicinal Chemistry, Vol. 38, No. 12 pp. 2023-2037, (June 1995)

Crystal, "Transfer of Genes to Humans: Early Lessons and Obstacles to Success." Science, Vol. 270, pp. 404-410, (Oct. 1995)

Stull et al. (Stull), "Antigene, Ribozyme, and Aptamer Nucleic Acid Drugs: Progress and Prospects." Pharmaceutical Research, Vol. 12, No. 4 pp. 465-481 (1995)

Claims 9 through 11 and 26 through 47 stand rejected under 35 U.S.C. § 112, first paragraph (enablement) and claims 26 through 41 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. We reverse both rejections.

BACKGROUND

The p53 gene is known to suppress tumors. Specification, page 3. Mutations of the p53 gene cannot only eliminate the tumor suppressor activity but can also stimulate growth of malignancies. Id. Ribozymes are RNA molecules, many of which have a specific catalytic domain that possesses endonuclease activity. Specification page 4. The present invention is explained at page 5, lines 29-34 as follows:

> This invention generally relates to expression constructs that express a ribozyme that inactivates pre-mRNA of the mutant p53 and methods for their use. More specifically, the present invention provides a retroviral vector-mediated system that can be used to transduce various hammerhead ribozymes into cancer cells, such as human lung cancer cells.

A second embodiment of the present invention is explained at page 6, lines 10-15 of the specification as follows:

> It also is contemplated, as part of the present invention, to provide a replacement p53 gene that exhibits wild-type p53 activity. This replacement gene is engineered to avoid the action of the ribozyme, for example, by being provided in the form of a cDNA or a construct otherwise lacking the ribozyme target.

As seen from the representative claims reproduced above, the disclosed invention is claimed in this application in two forms, viz, a pharmaceutical composition and method for treating a mammal with cancer. All claims require the presence or use of a p53-specific ribozyme.

DISCUSSION

1. Claim Definiteness

The examiner states at page 9 of the Examiner's Answer that:

> Claim 26 and those dependent thereon are indefinite because it is not clear how the objective stated in the preamble of claim 26 is to be achieved. It is

> recommended that the terminal step of the method claim set forth how the objective stated in the preamble is to be achieved.

It is not clear to us what point the examiner is trying to make. The "objective" stated in the preamble of claim 26 is achieved through use of steps (i), (ii), and (iii) set forth in the body of claim 26.

The rejection of claims 26 through 41 under 35 U.S.C. § 112, second paragraph is reversed.

2. Enablement

The examiner's position is aptly summarized at page 5 of the Examiner's Answer where the examiner states that "[t]he successful therapeutic application of nucleic acid-based therapeutics is unknown in the prior art." The examiner relies upon four documents in support of this conclusion. Of the four, we find Christoffersen and Stull to be the most relevant in that they specifically address the use of ribozymes as human therapeutic agents. Crystal and Orkin are less relevant because they are not directed to ribozyme technology. Thus, we shall focus on Christoffersen and Stull.

As seen from its title, "Ribozymes as Human Therapeutic Agents," Christoffersen provides a summary of ribozyme technology at or around the filing date of this application, September 1, 1995. The third section of Christoffersen is entitled "Proof of Principle." Christoffersen states,

> To demonstrate the potential of ribozymes, their abilities to cleave mRNA targets must be correlated with biochemical and physiological changes that result from target cleavage. Many studies now have been published which illustrate these proofs of principle. [Christoffersen, page 2025]

The next two sections of Christoffersen are entitled "Ribozyme and Active Selection" and "Delivery of Ribozymes to Cells." In these sections, Christoffersen documents work which identifies active ribozymes as well as work which establishes the stability of ribozymes in biological environments. The fifth section of Christoffersen is entitled "Delivery of Ribozymes to the Cells." This section concludes:

> Viral delivery of ribozymes and other oligonucleotides is at an early stage of development, and investigations to date in therapeutic settings are described below. While any of the viral vectors is applicable in principle, more experience is needed. For example, targeting ribozyme-containing vectors to particular tissues or cells may be important. This may be accomplished via a physical method such as an aerosol to the lung epithelium, to a target tissue ex vivo such as bone marrow which is then reinfused, by widespread delivery via a vector such as adeno-associated virus which would infect many cells and tissues, or by intracellular targeting. (Reference citation omitted) [Christoffersen, page 2029]

The sixth section of Christoffersen is entitled "Therapeutic Applications."[1] Importantly, Christoffersen states:

> Therapeutic applications of ribozymes are potentially quite broad but have thus far been applied to situations involving inhibition of overexpression of a gene. The gene target may be foreign, as in a viral infection, or may be a normal gene which has undergone mutation such as an activated protooncogene.
>
> The most obvious areas of therapy at this time are viral infections, both acute and chronic; cancer where an oncogene product is known; and various disease states where overexpression of a particular gene is associated with a disease state. Examples of the latter include restenosis and other cardiovascular diseases, transplant rejection, osteoarthritis, and immunological diseases. This review will concentrate on examples from viral infections and cancer. [Christoffersen, page 2029]

The final passage of Christoffersen is entitled "Future Aspects." Importantly, Christoffersen states:

> As demonstrated above, control of gene expression using ribozymes holds the potential to provide an important new paradigm for human therapeutics.

[1] This section begins at page 2029 of Christoffersen and is erroneously numbered IV instead of VI.

> In the past several years, substantial progress has been made in translating this potential into reality. Cell culture and in vivo efficacy have been demonstrated in a number of systems, and therapeutic applications in viral diseases and cancer have been initiated. However, to complete this process, a number of issues need to be resolved. The current status of these issues, both for ribozymes and other oligonucleotide therapeutic approaches, is discussed below. [Christoffersen, pp. 2032-2033.]

Christoffersen goes on to discuss specificity, kinetic considerations, cleavage and turnover, delivery, and therapeutic potential.

Stull discusses antigene, ribozyme and aptamer nucleic acid drugs. Stull concludes with a section entitled "Obstacles To Application Of Nucleic Acid Drugs In Vivo." In relevant part, Stull states:

> It is clear, however, that application of these expensive compounds in vivo requires many problems be solved, some of which have been discussed above in conjunction with studies performed in cell culture, but particularly those related to delivery in vivo of nucleic acids to the cytoplasm of specific cells. The delivery challenge can be subdivided into problems with persistence of effect, access to the target cells and efficient cytoplasmic delivery of the drug. [Stull, page 476.]

On the basis of these and other teachings, the examiner concludes:

> Due to the lack of specific guidance and appropriate working examples presented in the specification and due to lack of guidance available from the prior art, a skilled artisan would be required to engage in experimentation to reduce the claimed invention to practice in a therapeutic capacity. Due to the unpredictable nature of the art, this experimentation is expected to be extensive and of a trial-and-error nature.... Since the skilled artisan could not have reduced the claimed invention to practice in a therapeutic or pharmaceutical capacity without engaging in undue experimentation, the specification fails to provide an enabling disclosure. [Examiner's Answer, pp. 8-9.]

In reviewing Christoffersen and Stull, we find that they undermine the examiner's position to a greater extent than they support the examiner's position. As seen from Christoffersen, ribozymes have been accepted by those whose skilled in this art in

principle as human therapeutic agents. The problems identified in Christoffersen and Stull relied upon by the examiner go more towards whether ribozymes will be useful in a clinical setting. As seen from Christoffersen, "in vivo efficacy [has] been demonstrated in a number of systems." Christoffersen, page 2033. In our view, the problems relied upon by the examiner such as specificity, cleavage and turnover and delivery of the ribozyme go more toward considering how effective this technology will be in treating cancer, not that ribozyme technology is without effect to any degree in treating cancer. In support of this point, we note the following passage from Stull:

> The persistence of effect issue arises because none of the modalities proposed to date can eliminate the disease/target. Thus suppression of disease will require the continued presence of the agent until the disease is cured or the condition is eliminated. In non-gene therapy approaches, dosing via the intravenous route will be needed at a frequent interval, circa days, if therapeutic levels of the agent are to persist in the body. Although certain sites, such as the eye, may permit less frequent administration of the agent, in most cases, repeated administration via injection will be required. This makes treatment of chronic disorders, such as HIV infection, with synthetic nucleic acid drugs a difficult undertaking. [Stull, pp.476-477.]

Enablement under 35 U.S.C. § 112, first paragraph, does not require that a claimed invention be perfected or optimized. Rather, enablement only requires that one skilled in the art be able to make and use the claimed invention without undue experimentation. Here, the examiner has not raised any objection in regard to the ability of those skilled in the art to make any of the expression constructs required by the claims on appeal or the ability of those skilled in the art to perform the steps set forth in the method claims. In responding to appellants' arguments on appeal, the examiner states that his concern is not in regard to utility under section 101. Examiner's Answer, page 11 ("The examiner has not argued that the invention lacks utility and has not

rejected any claims under 35 U.S.C. § 101."). Having conceded that one of ordinary skill in the art would recognize that the method set forth in claim 26 on appeal and the pharmaceutical composition of claim 9 have practical utility, it is not clear why the examiner is questioning that one skilled in the art would not be able "use" the claimed invention under 35 U.S.C. § 112, first paragraph.

In reaching our decision, we have considered the declaration filed by co-appellant Dr. Jack A. Roth under 37 CFR § 1.132 attached as Exhibit B to the Appeal Brief. As noted by the examiner, the declaration was submitted in a different application and does not directly address the application of a p53-specific ribozyme. However, we believe the declaration warrants some weight in considering the enablement of the claims before us for consideration in this appeal. The declaration was submitted in Application No. 07/960,513, now issued as U.S. Patent No. 6,017,524 ('524 patent). Claim 9 of the '523 patent reads as follows:

> 9. A method for treating cancer in a human patient comprising directly introducing into a p53-deficient tumor cell of the patient a retroviral expression vector dispersed in a pharmaceutical diluent, wherein said expression vector comprises a gene expression unit which comprises a wild-type p53 gene under the control of a β-actin promoter, the gene expression unit being positioned to effect transcription of the gene in an orientation opposite that of retroviral transcription, and wherein expression of p53 by said expression vector effective to inhibit the growth of said tumor cell.

As seen, claim 9 of the '524 patent is directed to the method for treating cancer which comprises introducing a gene expression unit which comprise a wild-type p53 gene such that transcription is effected in an orientation opposite that of retroviral transcription, i.e., antisense technology. Stull raises the same concerns in regard to antisense technology as it does in regard to ribozyme technology. The '524 patent was

issued on an application filed October 13, 1992. We think the issuance of the '524 patent provides some evidence that the art of using nucleic acids for therapeutic uses was not as unpredictable as of September 1, 1995, as the examiner would have it.

The decision of the examiner is reversed.

REVERSED

William F. Smith
Administrative Patent Judge

Douglas W. Robinson
Administrative Patent Judge

Donald E. Adams
Administrative Patent Judge

) BOARD OF PATENT
) APPEALS AND
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ELD

United States Court of Appeals for the Federal Circuit

01-1324

CATALINA MARKETING INTERNATIONAL, INC.,

Plaintiff-Appellant,

v.

COOLSAVINGS.COM, INC.,

Defendant-Appellee.

Steven Z. Szczepanski, Jenkens & Gilchrist, of Chicago, Illinois, argued for plaintiff-appellant. With him on the brief were Mary Jo Boldingh, Russell J. Genet, and Michael K. Nutter.

Dean D. Niro, Niro, Scavone, Haller & Niro, of Chicago, Illinois, argued for defendant-appellee. With him on the brief were Thomas G. Scavone and Christopher J. Lee.

Appealed from: United States District Court for the Northern District of Illinois

Judge John W. Darrah

United States Court of Appeals for the Federal Circuit

01-1324

CATALINA MARKETING INTERNATIONAL, INC.,

Plaintiff-Appellant,

v.

COOLSAVINGS.COM, INC.,

Defendant-Appellee.

DECIDED: May 8, 2002

Before MAYER, Chief Judge, RADER, and PROST, Circuit Judges.

RADER, Circuit Judge.

On summary judgment, the United States District Court for the Northern District of Illinois held that Coolsavings.com, Inc. (Coolsavings) did not infringe, either literally or by equivalents, the claims of Catalina Marketing International, Inc.'s (Catalina's) U.S. Patent No. 4,674,041 (the '041 patent). Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc., No. 00C 2447, slip op. at 6-7 (N.D. Ill. Mar. 27, 2001). In the alternative, the district court applied prosecution history estoppel to bar Catalina from seeking equivalents on the location of the claimed terminals. Id. Because the district court erroneously relied on non-limiting language in the preamble of Claim 1 and misapplied prosecution history estoppel, this court affirms-in-part, reverses-in-part, vacates-in-part, and remands.

I.

The '041 patent, filed on September 15, 1983, claims a selection and distribution system for discount coupons. In a preferred embodiment, the system dispenses coupons to consumers at remote, kiosk-like terminals connected to a central host computer system. When a consumer activates the terminal in a retail outlet, the terminal displays available coupons on the screen. The consumer selects a coupon and a printer connected to the terminal prints it. The terminal selectively communicates with the central computer system to acquire coupon information for display. When the number of dispensed coupons for a certain product reaches a limit specified by a coupon provider, the central computer system stops providing that particular coupon. Figure 3a depicts the terminal:

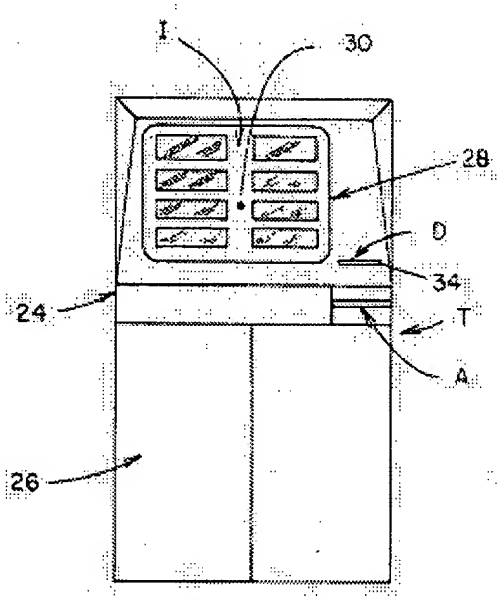

FIG 3a

There are two independent claims at issue, namely Claims 1 and 25, which read as follows:

> 1. A systen [sic] for controlling the selection and dispensing of product coupons at a plurality of remote terminals <u>located at predesignated sites such as consumer stores</u> wherein each terminal comprises:
>
> activation means for activating such terminal for consumer transactions;
>
> display means operatively connected with said activation means for displaying a plurality of coupons available for selection;

selection means operatively connected with said display means provided to permit selection of a desired displayed coupon by the consumer;

print means operatively connected with said selection means for printing and dispensing the coupon selected by the consumer; and

control means operatively connected with said display, means for monitoring each consumer transaction and for controlling said display means to prevent the display of coupons having exceeded prescribed coupon limits.

25. A system for controlling the selection and dispensing of product coupons at a plurality of remote terminals located at predesignated sites such as consumer stores, comprising:

a plurality of free standing coupon display terminals located at predesignated sites such as consumer stores, each of said terminals being adapted for bidirectional data communication with a host central processing unit;

each of said terminals comprising

activation means for activating such terminals for consumer use by insertion of a credit card or other card having customer account information stored on a magnetic strip;

display means operatively connected with said activation means for displaying a plurality of coupons;

selection means operatively connected with said display means for providing for the selection of a desired displayed coupon by a consumer;

print means operatively connected with said selection means for printing and dispensing the coupons selected;

terminal control means operatively connected with said display means and print means for continuously monitoring each customer transaction and for controlling said display and print means in response to prescribed coupon limits;

means for storing consumer transactions and for periodically communicating customer transactions to said host central processing unit;

said host central processing unit including means for the transmitting to each terminal particular information for each coupon; and

said host central processing unit further including means for periodically transmitting to each terminal coupon limits such as and including expiration date, and total number of coupons to be dispensed.

'041 patent, col. 30, ll. 46-65 and col. 32, l. 67 – col. 33, l. 36 (emphases added).

During prosecution of the '041 patent, the examiner rejected all of the original claims as obvious in light of U.S. Patent No. 4,449,186 (the Kelley patent), which

disclosed a terminal system for dispensing airline tickets. The examiner concluded that the only difference between the applicants' claimed invention and the Kelley patent was the location of the coupon terminal. In response, the applicants provided a general overview of the invention and amended the structural limitations of Claims 1 and 25 to distinguish the Kelley patent. The examiner again rejected all of the pending claims.

Responsive to the second rejection, the applicants again amended Claims 1 and 25, and submitted several declarations to bolster their assertion of nonobviousness. The applicants did not amend the claim language relating to the location of the terminals. Although stating that their invention involved terminals "located in stores" for the dispensing of coupons "on-site," the applicants also did not argue that the location of the terminals in stores distinguished the invention from the Kelley patent.

Coolsavings uses a web-based coupon system to monitor and control the distribution of coupons from its www.coolsavings.com website. After registering with the coolsavings.com website and providing demographic data, users can browse the website for available coupons. Users then select and print coupons for in-store redemption. Additionally, in some cases, users may access a coupon provider's website for on-line redemption of a coupon offer for on-line products. A centralized computer system stores coupon and user data. Users may access the Coolsavings system from any Internet-accessible computer by simply logging onto the coolsavings.com website. Coolsavings received U.S. Patent No. 5,761,648 (the '648 patent) for its web-based coupon system. Catalina's '041 patent was cited during prosecution of the '648 patent.

Catalina sued Coolsavings, alleging that Coolsavings' web-based coupon system infringed the '041 patent. The district court construed the claim language "located at predesignated sites such as consumer stores," and held that Coolsavings did not infringe, either literally or by equivalents, the construed language. After determining that

Coolsavings did not infringe under the doctrine of equivalents, the district court then alternatively held that prosecution history estoppel barred Catalina from seeking equivalents on the location of the terminals.

On appeal, Catalina argues that the disputed language, which appears only in the preamble of Claim 1, is not a limitation because it merely states an intended use for the claimed system. Alternatively, Catalina contends that the district court misconstrued the "located at predesignated sites such as consumer stores" claim language. In addition, Catalina asserts that prosecution history estoppel does not bar equivalents when the applicants did not amend the disputed language or argue patentability based on that language. This court has jurisdiction under 28 U.S.C. § 1295(a)(1) (1994).

II.

This court reviews a district court's grant of summary judgment without deference. Johns Hopkins Univ. v. Cellpro, Inc., 152 F.3d 1342, 1353, 47 USPQ2d 1705, 1713 (Fed. Cir. 1998). Thus, this court must decide for itself "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c); Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986). In so doing, this court draws all justifiable inferences in the nonmovant's favor. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 255 (1986).

Before determining whether an accused device or process infringes, a court must first construe the claim language to determine the meaning and scope of the claims. Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1454, 46 USPQ2d 1169, 1172 (Fed. Cir. 1998) (en banc). Claim language defines claim scope. SRI Int'l. v. Matsushita Elec. Corp. of Am., 775 F.2d 1107, 1121, 227 USPQ 577, 585 (Fed. Cir. 1985) (en banc). Generally, claim language receives its plain, ordinary meaning as used in the relevant art. Toro Co.

v. White Consol. Indus., Inc., 199 F.3d 1295, 1299, 53 USPQ2d 1065, 1067 (Fed. Cir. 1999). When construing claim scope, courts may consult the specification, the prosecution history, and other relevant evidence. Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1309, 51 USPQ2d 1161, 1169 (Fed. Cir. 1999). Claim construction is a question of law, which this court reviews without deference. Cybor Corp., 138 F.3d at 1456.

A.

The district court's claim construction focused solely on the phrase "located at predesignated sites such as consumer stores." This phrase appears in the preamble of Claim 1, and in both the preamble and body of Claim 25. The district court construed this disputed phrase without discussion as to whether the phrase, which appears only in the preamble of Claim 1, was indeed a limitation of Claim 1.

Whether to treat a preamble as a limitation is a determination "resolved only on review of the entire[ ] . . . patent to gain an understanding of what the inventors actually invented and intended to encompass by the claim." Corning Glass Works v. Sumitomo Electric U.S.A., Inc., 868 F.2d 1251, 1257, 9 USPQ2d 1962, 1966 (Fed. Cir. 1989); see also Applied Materials, Inc. v. Advanced Semiconductor Materials Am., Inc., 98 F.3d 1563, 1572-73, 40 USPQ2d 1481, 1488 (Fed. Cir. 1996) ("Whether a preamble stating the purpose and context of the invention constitutes a limitation of the claimed process is determined on the facts of each case in light of the overall form of the claim, and the invention as described in the specification and illuminated in the prosecution history.").

In general, a preamble limits the invention if it recites essential structure or steps, or if it is "necessary to give life, meaning, and vitality" to the claim. Pitney Bowes, 182 F.3d at 1305. Conversely, a preamble is not limiting "where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a

purpose or intended use for the invention." Rowe v. Dror, 112 F.3d 473, 478, 42 USPQ2d 1550, 1553 (Fed. Cir. 1997).

No litmus test defines when a preamble limits claim scope. Corning Glass, 868 F.2d at 1257. Some guideposts, however, have emerged from various cases discussing the preamble's effect on claim scope. For example, this court has held that Jepson claiming generally indicates intent to use the preamble to define the claimed invention, thereby limiting claim scope. Rowe, 112 F.3d at 479; Epcon Gas Sys., Inc. v. Bauer Compressors, Inc., 279 F.3d 1022, 1029, 61 USPQ2d 1470, 1475 (Fed. Cir. 2002). Additionally, dependence on a particular disputed preamble phrase for antecedent basis may limit claim scope because it indicates a reliance on both the preamble and claim body to define the claimed invention. Bell Communications Research, Inc. v. Vitalink Communications Corp., 55 F.3d 615, 620, 34 USPQ2d 1816, 1820 (Fed. Cir. 1995) ("[W]hen the claim drafter chooses to use both the preamble and the body to define the subject matter of the claimed invention, the invention so defined, and not some other, is the one the patent protects."). Likewise, when the preamble is essential to understand limitations or terms in the claim body, the preamble limits claim scope. Pitney Bowes, 182 F.3d at 1306.

Further, when reciting additional structure or steps underscored as important by the specification, the preamble may operate as a claim limitation. Corning Glass, 868 F.2d at 1257 (limiting claim scope to "optical waveguides" rather than all optical fibers in light of specification); General Electric Co. v. Nintendo Co., 179 F.3d 1350, 1361-62, 50 USPQ2d 1910, 1918-19 (Fed. Cir. 1999) (limiting claim scope to a "raster scanned display device" rather than all display systems in view of specification's focus on the prior art problem of displaying binary data on a raster scan display device); Rowe, 112 F.3d at 479-80; Applied Materials, 98 F.3d at 1573.

Moreover, clear reliance on the preamble during prosecution to distinguish the claimed invention from the prior art transforms the preamble into a claim limitation because such reliance indicates use of the preamble to define, in part, the claimed invention. See generally Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc., 246 F.3d 1368, 1375, 58 USPQ2d 1508, 1513 (Fed. Cir. 2001) (A preamble may limit when employed to distinguish a new use of a prior art apparatus or process.). Without such reliance, however, a preamble generally is not limiting when the claim body describes a structurally complete invention such that deletion of the preamble phrase does not affect the structure or steps of the claimed invention. IMS Tech., Inc. v. Haas Automation, Inc., 206 F.3d 1422, 1434, 54 USPQ2d 1129, 1136-37 (Fed. Cir. 2000) (preamble phrase "control apparatus" does not limit claim scope where it merely gives a name to the structurally complete invention). Thus, preamble language merely extolling benefits or features of the claimed invention does not limit the claim scope without clear reliance on those benefits or features as patentably significant. STX, LLC v. Brine, Inc., 211 F.3d 588, 591 (Fed. Cir. 2000) (preamble stating that invention provides "improved playing and handling characteristics" is not a limitation); Bristol-Myers, 246 F.3d at 1375 (steps of claimed method are performed the same way regardless of whether, as stated in the preamble, a reduction of hematologic toxicity occurs).

Moreover, preambles describing the use of an invention generally do not limit the claims because the patentability of apparatus or composition claims depends on the claimed structure, not on the use or purpose of that structure. In re Gardiner, 171 F.2d 313, 315-16, 80 USPQ 99, 101 (CCPA 1948) ("It is trite to state that the patentability of apparatus claims must be shown in the structure claimed and not merely upon a use, function, or result thereof."). Indeed, "[t]he inventor of a machine is entitled to the benefit of all the uses to which it can be put, no matter whether he had conceived the idea of the

use or not." Roberts v. Ryer, 91 U.S. 150, 157 (1875). More specifically, this means that a patent grants the right to exclude others from making, using, selling, offering to sale, or importing the claimed apparatus or composition for any use of that apparatus or composition, whether or not the patentee envisioned such use. See 35 U.S.C. § 271 (1994). Again, statements of intended use or asserted benefits in the preamble may, in rare instances, limit apparatus claims, but only if the applicant clearly and unmistakably relied on those uses or benefits to distinguish prior art. Likewise, this principle does not mean that apparatus claims necessarily prevent a subsequent inventor from obtaining a patent on a new method of using the apparatus where that new method is useful and nonobvious.

Perhaps a hypothetical best illustrates these principles: Inventor A invents a shoe polish for shining shoes (which, for the sake of example, is novel, useful, and nonobvious). Inventor A receives a patent having composition claims for shoe polish. Indeed, the preamble of these hypothetical claims recites "a composition for polishing shoes." Clearly, Inventor B could not later secure a patent with composition claims on the same composition because it would not be novel. See In re Schreiber, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997). Likewise, Inventor B could not secure claims on the method of using the composition for shining shoes because the use is not a "new use" of the composition but, rather, the same use – shining shoes. See Bristol-Myers, 246 F.3d at 1375; In re King, 801 F.2d 1324, 1327, 231 USPQ 136, 138 (Fed. Cir. 1986).

Suppose Inventor B discovers that the polish also repels water when rubbed onto shoes. Inventor B could not likely claim a method of using the polish to repel water on shoes because repelling water is inherent in the normal use of the polish to shine shoes. Id. at 1326 ("'[I]f a previously patented device, in its normal and usual operation, will

perform the function [claimed] in a subsequent [ ] process patent, then such [ ] process patent [is] . . . anticipated by the former patented device.") (quoting In re Ackenback, 45 F.2d 437, 439, 7 USPQ 268, 270 (CCPA 1930)); see also Bristol-Myers, 246 F.3d at 1375. In other words, Inventor B has not invented a "new" use by rubbing polish on shoes to repel water. Upon discovering, however, that the polish composition grows hair when rubbed on bare human skin, Inventor B can likely obtain method claims directed to the new use of the composition to grow hair. See 35 U.S.C. § 101 (1994) ("Whoever invents or discovers any new and useful process ... may obtain a patent therefor."); 35 U.S.C. § 100(b) (1994) ("The term 'process' means process, art or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material."). Hence, while Inventor B may obtain a blocking patent on the use of Inventor A's composition to grow hair, this method patent does not bestow on Inventor B any right with respect to the patented composition. Even though Inventor A's claim recites "a composition for polishing shoes," Inventor B cannot invoke this use limitation to limit Inventor A's composition claim because that preamble phrase states a use or purpose of the composition and does not impose a limit on Inventor A's claim.

In this case, the claims, specification, and prosecution history of the '041 patent demonstrate that the preamble phrase "located at predesignated sites such as consumer stores" is not a limitation of Claim 1. The applicant did not rely on this phrase to define its invention nor is the phrase essential to understand limitations or terms in the claim body. Although the specification refers to terminals located at points of sale, and even once states that terminals may be placed in retail stores, the specification, in its entirety, does not make the location of the terminals an additional structure for the claimed terminals. See '041 patent, col. 1, l. 67 - col. 2, l. 37 and col. 4, ll. 65-67.

The applicants also did not rely on the preamble phrase to distinguish over the Kelly patent. Rather, the examiner expressly rejected the claims on the basis that the location of the terminals in stores was not patentably significant. In response, the applicants amended structural limitations in the claim body to distinguish the Kelly patent. Thus, while the applicants stated during prosecution that their invention involved terminals "located in stores" for the dispensing of coupons "on-site," such statements, without more, do not indicate a clear reliance on the preamble to distinguish the prior art, especially where the examiner's initial rejection considered terminal location insignificant for patentability.

Moreover, deletion of the disputed phrase from the preamble of Claim 1 does not affect the structural definition or operation of the terminal itself. The claim body defines a structurally complete invention. The location of the terminals in stores merely gives an intended use for the claimed terminals. As already noted, the applicants did not rely on this intended use to distinguish their invention over the prior art.

In this case, the disputed preamble language does not limit Claim 1 -- an apparatus claim. To hold otherwise would effectively impose a method limitation on an apparatus claim without justification. Accordingly, this court holds that the district court erroneously treated the preamble as a limitation of Claim 1.

B.

While the phrase "located at predesignated sites such as consumer stores" appears only in the preamble of Claim 1, this language appears in both the preamble and body of Claim 25. Hence, the applicants specifically included this language in the claim not once, but twice. By virtue of its inclusion in the body of Claim 25, this phrase limits Claim 25. This court, therefore, must determine whether the district court's construction of the disputed phrase is correct as a matter of law.

In interpreting this language, the district court found that "predesignate" means "to designate beforehand," and that "site" means "the original or fixed position of a thing." Accordingly, the district court held that the ordinary meaning of "predesignated site" is "to designate beforehand the original or fixed position of a thing." The district court found that the term "such as" means "of a kind or character about to be indicated, suggested, or exemplified; for instance." The district court then considered whether the phrase "such as a consumer store" means that the terminals may be located anywhere or only "at the point of sale." The district court concluded that the terminals had "to be placed at a predesignated site at the point of sale, i.e., a consumer store."

Although agreeing with the dictionary definition of "predesignated site," Catalina argues that the predesignation of sites refers to "the connecting of and accepting of the terminal by the host computer." According to Mr. Wicker, Catalina's expert, "predesignated sites" "indicates that certain sites have been designated, and [ ] that they have been designated at a point in time prior to . . . 'the selection and dispensing of product coupons.'" Catalina further contends that the district court erred by equating "point of sale" with "consumer store." According to Catalina, the genus indicated by the species "consumer stores" is a "point of sale" location.

The district court correctly held that the ordinary meaning of "predesignated site" is "to designate beforehand the original or fixed position of a thing." Thus, the claim requires designation of a terminal site before location of a terminal at that site. Catalina's argument that "predesignated sites" refers to the recognition of a terminal by a host computer at some point before coupon selection ignores the physical dimension indicated by the phrase "located at" immediately preceding "predesignated sites." Recognition simply does not amount to predesignation. Thus, a coupon dispensing entity must

designate a location for a terminal before placing it at that site. This claim language limits the scope of the claims.

The district court correctly found that the term "such as" means "of a kind or character about to be indicated, suggested, or exemplified; for instance." Despite correctly characterizing "such as" as exemplary language, the district court erroneously equated "point of sale" with "consumer store." "Such as" introduces an example of a broader genus rather than limiting the genus to the exemplary species. Moreover, the specification of the '041 patent uses the phrase "such as consumer stores" as an example of a possible point of sale location. See, e.g., '041 patent, col. 1, l. 67 – col. 2, l. 4, col. 2, ll. 32-38, and col. 4, ll. 65-67. As discussed above, the applicants stated during prosecution that their invention involved terminals "located in stores" for the dispensing of coupons "on-site." This descriptive language during the acquisition of the patent does not make the store location more than an example of a point of sale location.

This court thus holds that the phrase "located at predesignated sites such as consumer stores" requires designation of the physical site of the terminal before location of the terminal at a point of sale location.

III.

After claim construction, the fact finder compares the properly construed claims to the accused device or process. Cybor Corp., 138 F.3d at 1454. To prove infringement, the patentee must show that the accused device meets each claim limitation either literally or under the doctrine of equivalents. Seal-Flex, Inc. v. Athletic Track and Court Const., 172 F.3d 836, 842, 50 USPQ2d 1225, 1228 (Fed. Cir. 1999). Literal infringement requires the patentee to prove that the accused device contains each limitation of the asserted claim. Mas-Hamilton Group v. LaGard, Inc., 156 F.3d 1206, 1211, 48 USPQ2d 1010, 1014-15 (Fed. Cir. 1998). Infringement under the doctrine of equivalents requires the

patentee to prove that the accused device contains an equivalent for each limitation not literally satisfied. Dawn Equip. Co. v. Kentucky Farms, 140 F.3d 1009, 1015, 46 USPQ2d 1109, 1113 (Fed. Cir. 1998).

A determination of infringement, whether literal or under the doctrine of equivalents, is a question of fact. Bai v. L & L Wings, Inc., 160 F.3d 1350, 1353, 48 USPQ2d 1674, 1676 (Fed. Cir. 1998). Summary judgment of no literal infringement is proper when, construing the facts in a manner most favorable to the nonmovant, no reasonable jury could find that the accused system meets every limitation recited in the properly construed claims. Bai, 160 F.3d at 1353.

A.

Based on its construction of the phrase "located at predesignated sites such as consumer stores," the district court held that Coolsavings' system did not literally infringe Claims 1 or 25 of the '041 patent. Because this phrase does not limit Claim 1 and the district court did not further construe Claim 1, this court vacates the judgment of no literal infringement of Claim 1 and remands for claim construction and appropriate infringement proceedings. With respect to Claim 25, this court construed the phrase "located at predesignated sites such as consumer stores" to require that the physical position of the terminal be designated before placement of the terminal at a point of sale location. For Coolsavings to be liable for literal infringement Coolsavings' accused system must designate the physical position of the terminals before location of the terminals at a point of sale. Coolsavings' system, however, does not designate (or even recognize) the physical position of computers connecting to its website; thus, Coolsavings' system does not literally satisfy this limitation of Claim 25. Under the proper claim construction, this court therefore affirms the district court's holding that Coolsavings' system does not literally infringe Claim 25 of the '041 patent. Because this holding is dispositive on literal

infringement, this court need not opine on Catalina's argument that an Internet-accessible home computer constitutes a point of sale location.

B.

"An accused device that does not literally infringe a claim may still infringe under the doctrine of equivalents if each limitation of the claim is met in the accused device either literally or equivalently." Cybor Corp., 138 F.3d at 1459. An element in the accused product is equivalent to a claim limitation if the differences between the two are "insubstantial" to one of ordinary skill in the art. Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 40 (1997). Insubstantiality may be determined by whether the accused device "performs substantially the same function in substantially the same way to obtain the same result" as the claim limitation. Graver Tank & Mfg. Co. v. Linde Air Prods. Co., 339 U.S. 605, 608 (1950).

Because the district court only construed a non-limiting preamble phrase and has not further construed the limitations of Claim 1, this court vacates and remands for further proceedings concerning infringement under the doctrine of equivalents on Claim 1. The record evidence does not sufficiently inform as to whether Coolsavings' system varies insubstantially from Claim 25's requirement of terminals "located at predesignated sites such as consumer stores." In other words, the doctrine of equivalents requires a factual assessment of whether Coolsavings' system, which of necessity determines an Internet address for computers accessing its website, is insubstantially different from the placement of terminals at predesignated points of sale. This court, therefore, vacates and remands the question of infringement under the doctrine of equivalents on Claim 25.

IV.

Prosecution history estoppel prevents the doctrine of equivalents from recapturing subject matter surrendered during prosecution. Litton Sys., Inc. v. Honeywell, Inc., 140

F.3d 1449, 1458, 46 USPQ2d 1321, 1327 (Fed. Cir. 1998). "The relevant inquiry is whether a competitor would reasonably believe that the applicant had surrendered the relevant subject matter." Cybor Corp., 138 F.3d at 1457. The applicability of prosecution history estoppel is a legal question, which this court reviews without deference. Id. at 1460.

The district court concluded that prosecution history estoppel barred Catalina from seeking equivalents for the "located at predesignated sites such as consumer stores" limitation. While its analysis is somewhat unclear, the district court appears to base its conclusion on the applicants' statements during prosecution that their invention involved terminals "located in stores" for the dispensing of coupons "on-site."

As discussed above, the applicants did not amend this language regarding the location of the terminals. In addition, the applicants did not argue that the location of terminals would distinguish the invention from the prior art. Undeniably, such an argument would have failed given the examiner's express statement that terminal location was not significant to the patentability inquiry. In sum, the applicant did not, clearly or otherwise, surrender subject matter by making allusions to terminal location. This court, therefore, reverses the district court's holding that prosecution history estoppel bars Catalina from seeking equivalents on this missing limitation of Claim 25.

CONCLUSION

Because the district court erroneously relied on non-limiting language in the preamble of Claim 1, this court vacates the district court's judgment of non-infringement of Claim 1, both literally and by equivalents, to give the district court the opportunity to construe the limitations of Claim 1. Although the district court erred in its construction of Claim 25, because the accused system does not infringe literally Claim 25, as properly construed, this court affirms the holding of no literal infringement of Claim 25. This court

vacates and remands the holding of no infringement of Claim 25 by equivalents because the trial court should have an opportunity to develop and assess the record under the proper claim construction. Finally, because the district court erred in determining that prosecution history estoppel bars equivalents on the terminal location, this court reverses that holding.

COSTS

Each party shall bear its own costs.

AFFIRMED-IN-PART, REVERSED-IN-PART, VACATED-IN-PART, and REMANDED